DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

M3007N

September 17, 1999

WARNING LETTER NYK 1999-68

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jack Hentel, M.D., Medical Director
DRA Imaging, P.C.
400 Westage Business Center Drive
Medical Arts Building at Westage
Fishkill, NY 12524

RE: Facility ID Number 111104

Dear Dr. Hentel:

Your facility was inspected on August 10, 1999 by a representative of the New York State Department of Health, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed serious regulatory problems involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility.

- ***Mammograms were processed when the [redacted] processor was out of limits on 5 days in July 1999.***

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet significant MQSA requirements. In addition, the inspector observed thirteen other days not included in the Level 1 observation, dating back to November 1998, when mammograms were processed while the processor was out of limits.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not

limited to, placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspension or revocation of your facility's FDA certificate; obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. The level 2 finding is:

- ***Failure to document corrective actions for the [redacted] processor QC failures at least once.***

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date that you receive this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- sample records that demonstrate proper recordkeeping requirements.

Please submit your response to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Olympic Towers, Suite 100, Buffalo, New York 14202.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have any questions about mammography facility requirements, you may contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely,

Brenda J. Holman
District Director